

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

D.J., TONI CORDOVA, <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	Civil Action No. 2:22-752
v.)	
)	
UNIVERSITY OF IOWA HOSPITALS)	Judge Cathy Bissoon
and CLINICS, <i>et al.</i> ,)	
)	
Defendants.)	

MEMORANDUM AND ORDER

I. MEMORANDUM

For the reasons stated below, the Motion to Dismiss (Doc. 112) Plaintiffs’ Amended Complaint filed by Defendants Ademola Abiose, Ann & Robert H. Lurie Children’s Hospital of Chicago, Maryam Banikazemi, Baylor College of Medicine, Cedars-Sinai Medical Center, Joel Charrow, Children’s Memorial Hospital, Cincinnati Children’s Hospital, Columbia University Medical Center, Duke University Health Center, Christine Eng, Massachusetts General Hospital, Michael Mauer, Manesh Patel, Ronald Scott, Katherine Sims, University of Alabama at Birmingham Medicine, University of Iowa Hospitals and Clinics, University of Minnesota, University of Washington Medicine, David Warnock, William Wilcox (“Moving Defendants”)¹ will be GRANTED.

¹ The only two non-moving Defendants are foreign Defendants, Dominique Germain and the University of Versailles (“Foreign Defendants”). There is no reflection on the docket indicating that the Foreign Defendants have been served.

A. Background

This case is a putative class action brought by sixteen named Plaintiffs on behalf of themselves or their decedents, based on harm allegedly sustained as a result of a shortage of a drug called Fabrazyme that began in 2009 and lasted until 2012. Am. Compl. (Doc. 111) ¶¶ 1-16, 62-83. Plaintiffs and/or their decedents suffered from Fabry disease, a rare, but lethal, heritable, genetic illness, in which a gene for an enzyme required to metabolize a certain fat is mutated or missing, resulting in the build-up of that fat in cells, blood vessels and organs, resulting in inflammation and, ultimately, death. Id. ¶¶ 1-16, 45-47. Fabrazyme is a synthetic version of the enzyme that is infused every two weeks to treat Fabry disease and mitigate its effects. Id. ¶¶ 48-50. Fabrazyme manufacturer, Sanofi Genzyme Corporation, is the sole FDA-approved supplier of enzyme replacement therapy for Fabry disease in the United States market. Id. ¶¶ 56-58.

The Moving Defendants include eleven medical centers (“Medical Center Defendants”) and their respective physicians (“Physician Defendants”). Four of the Medical Center Defendants – University of Iowa Hospitals and Clinics, University of Minnesota, University of Washington and University of Alabama at Birmingham – are public entities (“Public Entity Defendants”). The Physician Defendants did not treat any of the named Plaintiffs or their decedents; rather, they represented their respective medical institutions as members of the Fabry Stakeholder’s Working Group (“FSWG”), a group of experts convened by Sanofi Genzyme to prepare guidance to the Fabry community on the management of Fabrazyme supply during the drug shortage. Id. ¶¶ 84-106 and Exs. A, B. FSWG prepared two written guidance documents containing recommendations for temporary reductions of Fabrazyme use in light of the shortage. Id. Ex. A (issued in July 2009), Ex. B (issued in or around September 2009). The Amended

Complaint alleges that the Guidance was disseminated to all Fabry patients and their physicians, nationwide. *Id.* ¶¶ 95-99.

The Amended Complaint contains eight Counts. Counts 1-7 assert the following tort and constitutional claims against the non-public entity Defendants: (1) tort of failure to obtain informed consent; (2) breach of fiduciary duty; (3) Equal Protection violation (42 U.S.C. § 1981); (4) violation of 42 U.S.C. § 1983; (5) conspiracy to deprive rights from citizens (42 U.S.C. § 1985(3)); (6) negligent deprivation of rights of citizens (42 U.S.C. § 1986); and (7) Virginia wrongful death or survival action claims (Va. Code §§ 8.01-50, 8.01-25). Count Eight asserts a claim under the Interstate Compact Clause (U.S. Const., Art. 1, § 10, Cl. 3) against the Public Entity Defendants, and their respective physicians in their official capacities. *See generally* Am. Compl. ¶¶ 265-473. The lawsuit essentially contends that Defendants, through their participation in the FSWG, intentionally initiated a harmful experimental medical protocol on Plaintiffs and collected research data on low-dose Fabrazyme efficacy without Plaintiffs' informed consent.

On December 5, 2022, Defendants filed a Motion to Dismiss Plaintiff's Amended Complaint against all Moving Defendants under Federal Rule of Civil Procedure 12(b)(2) (Doc. 112), based upon lack of personal jurisdiction. The Motion to Dismiss additionally seeks dismissal of the claims against the Public Entity Defendants, and their respective physicians, pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(2), based on lack of standing and Eleventh Amendment immunity.² Plaintiffs oppose Defendants' Motion. (Doc. 116).

² Plaintiffs agree that Eleventh Amendment immunity applies to the Public Entity Defendants as to Counts 1-7 of the Amended Complaint, and, accordingly, with the exception of the University of Minnesota, did not name them as defendants as to those counts. In their Response Brief, Plaintiffs concede that the inclusion of the University of Minnesota in these counts was inadvertent. Thus, the Motion to Dismiss the University of Minnesota is granted as to Counts 1-

B. 12(b)(2) Motion to Dismiss – Lack of Personal Jurisdiction

Under Federal Rule of Civil Procedure 12(b)(2), the plaintiff has the burden of pleading sufficient facts to establish that the court has personal jurisdiction over the defendants. *See Pinker v. Roche Holdings, Ltd.*, 292 F.3d 361, 368 (3d Cir. 2002). When a defendant challenges personal jurisdiction, “the plaintiff must ‘prove by affidavits or other competent evidence that jurisdiction is proper.’” *Metcalf v. Renaissance Marine, Inc.*, 566 F.3d 324, 330 (3d Cir. 2009) (quoting *Dayhoff Inc. v. H.J. Heinz Co.*, 86 F.3d 1287, 1302 (3d Cir. 1996)). Absent jurisdictional discovery, however, a plaintiff need only “a prima facie case of personal jurisdiction,” and is entitled to have the allegations in the complaint taken as true and all factual disputes resolved in plaintiff’s favor. *Miller Yacht Sales, Inc. v. Smith*, 384 F.3d 93, 97 (3d Cir. 2004).

Here, the Amended Complaint asserts both federal-question and diversity jurisdiction. *See* Compl. ¶¶ 41-42.³ In diversity cases, the forum state’s law governs whether personal jurisdiction exists over an out-of-state defendant. *See Metcalfe*, 566 F.3d at 330. With federal question jurisdiction, the personal jurisdiction analysis lies under the Fifth Amendment’s due process clause. *See Max Daetwyler Corp. v. A.W. German, Corp.*, 762 F.2d 290, 293 (3d Ci. 1985). Nevertheless, when a pleading asserts claims under federal laws not authorizing nationwide service of process, the court may exercise personal jurisdiction only “to the extent

7 for this reason as well. Count 8 asserts an Interstate Compact Clause claim against only the Public Entity Defendants and their physicians in their official capacities. *See* Pl. Br. (Doc. 116) at 4.

³ The Amended Complaint further avers that the United States Supreme Court has original jurisdiction over the Interstate Compact Claim asserted at Count Eight. *See* Compl. ¶ 42.

[the defendant] is ‘subject to the jurisdiction’ of [the forum state’s] courts.” Fischer v. Fed. Express. Corp., 42 F.4th 366, 382 (3d Cir. 2022).

Pennsylvania’s long-arm statute permits the exercise of personal jurisdiction consistent with the Due Process Clause of the Fourteenth Amendment. *See* 42 Pa. Cons. Stat. Ann. § 5322(b). Due process requires a finding of minimum contacts with Pennsylvania such that the exercise of personal jurisdiction “does not offend traditional notions of fair play and substantial justice.” O’Connor v. Sandy Lane Hotel Co., 496 F.3d 312, 316-17 (3d Cir. 2007). Personal jurisdiction can be general or specific. *See id.* at 317. Specific jurisdiction typically is analyzed on a “claim by claim basis” and “must arise out of or relate to the defendant’s contacts with the forum.” Ford Motor Co. v. Mont. Eighth Jud. Dist. Ct., 141 S. Ct. 1017, 1024 (U.S. 2021); Marten v. Goodwin, 499 F.3d 290, 296 (3d Cir. 2007). To determine specific jurisdiction in this Circuit: (1) the defendant must have “purposefully directed its activities at the forum”; (2) the litigation must “arise out of or relate to” at least one of those activities; and (2) the exercise of jurisdiction otherwise must “comport with fair play and substantial justice.” O’Connor, 496 F.3d at 317. In the case of intentional torts, a plaintiff also can establish specific jurisdiction under the Calder “effects test.” *See* Calder v. Jones, 465 U.S. 783 (1984); Marten 499 F.3d at 297. The effects test is met when (1) the defendant committed an intentional tort; (2) the plaintiff felt the brunt of the harm in the forum such that the forum can be said to be the focal point of the harm; and (3) the defendant expressly aimed his conduct at the forum such that the forum can be said to be the focal point of the tortious activity. Marten, 499 F.3d at 297.

After careful consideration of the submissions of the parties, the Court agrees with Defendants that personal jurisdiction is lacking in this case. As an initial matter, Plaintiffs concede the absence of general jurisdiction over Defendants, and the Amended Complaint itself

confirms that none of the individual Defendants reside in Pennsylvania, and none of the Medical Center Defendants are incorporated, or have a principal place of business, in Pennsylvania. Am. Compl. ¶¶ 17-38. It likewise is undisputed that no federal statute authorizes nationwide service of process for any of Plaintiffs' claims. *See* Def. Reply Br. (Doc. 117) at 2; Pl. Br. (Doc. 116) at 6. Thus, Plaintiffs must establish specific jurisdiction under the minimum contacts analysis or the Calder effects test. This Plaintiffs have failed to do.

In short, Plaintiffs have not provided any evidence that any of the Moving Defendants purposefully directed any activities at Pennsylvania, let alone activities from which any of Plaintiffs' claims arose or to which they relate. Among other things, there is no evidence (or allegation) that the Moving Defendants: reside in Pennsylvania; have or had offices in Pennsylvania; have a bank account in Pennsylvania; are licensed to practice medicine in Pennsylvania; have ever treated patients in Pennsylvania; have directed advertising or marketing at Pennsylvania; have an authorized agent to receive service of process in Pennsylvania; own land in Pennsylvania; or have a mailing address, telephone number or fax number in Pennsylvania. In addition, only two of the named Plaintiffs purport to be Pennsylvania residents, neither of whom were patients of the Moving Defendants. Am. Compl. ¶¶ 44, 157.

The only Pennsylvania contact that Plaintiffs even remotely assert is the dissemination via FedEx of the two FSWG Guidance letters to all Fabry patients nationwide, including any patients who happened to live in Pennsylvania. Am. Compl. ¶¶ 44, 89, 102. Neither these contentions nor Plaintiffs' conclusory allegations that the FSWG interfered with their patient-doctor relationships and "forced its will on Pennsylvanians" establishes the requisite minimum contacts with the forum. There is no evidence that the FSWG panel physicians drafted the FSWG Guidance letters, mailed the Guidance to anyone, including patients and doctors in

Pennsylvania, or approved any such mailings. If anything, the record evidence refutes any such notion. *See* Def. Motion (Doc. 112) Exs. 1-3 (Wrigley, Wilcox and Sims Declarations). It likewise is undisputed that neither of the two FSWG meetings referenced in the Amended Complaint took place in Pennsylvania. Plaintiffs further ignore the plain language of the Guidance, which emphasizes that, “[u]ltimately, treatment decisions are at the discretion of the treating physician” and that “[p]atients should be encouraged to speak with their physicians about the treatment plan appropriate for them.” *See* Doc. 111, Exs. 1 & 2. Moreover, and, in any event, there is no evidence that Defendants purposely directed any activities at Pennsylvania itself, as opposed to at Plaintiffs. *See, e.g., Walden v. Fiore*, 571 U.S. 277, 285 (noting that “the ‘minimum contacts’ analysis looks to the defendant’s contacts with the forum state not the defendant’s contacts with persons who reside there”). For all of these reasons, Plaintiffs have failed to point to minimum contacts sufficient not “to offend traditional notions of fair play and substantial justice.”

The effects test likewise fails to establish personal jurisdiction over Plaintiffs’ intentional tort claims. Again, as Defendants state, even assuming the effects of the alleged intentional torts were felt by Pennsylvania patients, the effects test is not satisfied when, as here, a defendant’s “allegedly tortious conduct impacted a wider population beyond Pennsylvania’s borders.” Def. Reply (Doc. 117) at 7-8 (citing cases). Conclusory allegations aside, Plaintiffs have not made any showing that Pennsylvania had a unique relationship with Fabry disease or Fabry patients, or that the Guidance otherwise was aimed at Pennsylvania such that Pennsylvania could be said to be the focal point of the tortious activity.

In sum, there has been no showing that exercising personal jurisdiction over the Moving Defendants comports with Pennsylvania’s long-arm statute or that haling the Moving Defendants

into court in Pennsylvania would be fair, reasonable or consistent with federal due process standards for specific jurisdiction. Accordingly the Motion to Dismiss for lack of personal jurisdiction will be granted as to all Moving Defendants.⁴

II. ORDER

For these reasons, the Motion to Dismiss for lack of personal jurisdiction (**Doc. 112**) is **GRANTED WITHOUT PREJUDICE**. Should Plaintiffs choose to amend their complaint, they may do so by **October 17, 2023**. Given that Plaintiffs already have amended their Complaint once, they must make last, best efforts in these regards, because further opportunity for amendment will not be afforded. If Plaintiffs do not timely file an amended complaint, identifying a valid jurisdictional basis for proceeding, all claims against the Moving Defendants will be dismissed without prejudice to Plaintiffs' ability to re-file this lawsuit in an appropriate forum.

IT IS SO ORDERED.

September 29, 2023

s/Cathy Bissoon
Cathy Bissoon
United States District Judge

cc (via ECF email notification):

All Counsel of Record

⁴ As a result of the Court's findings as to personal jurisdiction, it is unnecessary to reach the Public Entity Defendants' alternative argument as to lack of standing under the Interstate Compact Clause.